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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 09/557,823 | 04/25/2000 | Richard J. Bucala | 0203H | 9900 |
| 24510 | 7590 | 02/10/2005 | EXAMINER | |
| PIPER MARBURY RUDNICK & WOLFE LLP | | | NOLAN, PATRICK J | |
| STEVEN B KELBER | | | ART UNIT | |
| 1200 NINETEENTH STREET, NW | | | PAPER NUMBER | |
| WASHINGTON, DC 20036-2412 | | | 1644 | |

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/557,823 | Applicant(s) BUCALA ET AL. | |
| | Examiner Patrick J. Nolan | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-68, 73-75 and 81-89 is/are pending in the application.
- 4a) Of the above claim(s) 83, 84 and 86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-68, 73-75, 81, 82, 85 and 87-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Part III DETAILED ACTION

1. Claims 66-68, 73-75 and 81-89 are pending.
2. Claims 83-84 and 86 stand withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03, for reasons set forth in the Paper mailed 8-12-04.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 66-68, 73-75, 81-82, 85, 87-89 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,786,168. (AA on the IDS submitted 9-24-02), for reasons set forth in the Paper mailed 8-12-04.

Applicant's arguments filed 11-12-04 have been fully considered but are not found persuasive.

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The declaration under 37 CFR 1.132 filed 11-12-04 is insufficient to overcome the rejection of claims 66-68, 73-75, 81-82, 85, 87-89 based upon 35 USC 102(e) as set forth in the last Office action because: for reasons set forth below.

Applicant argues the '168 patent provides no proof the anti-GIF antibody is actually MIF specific and that for the purpose of conducting a diagnostic test to detect MIF, the antibody must be MIF specific.

Antibody specificity is a property of antibodies to be able to specifically bind an antigen and therefore be able to remove or purify that which the antibody specifically binds to. The instant application teaches MIF is SEQ ID NO. 5 and they are claiming an immunoassay to detect a protein containing SEQ ID NO. 5 that has MIF activity. The prior art teaches an antibody that specifically binds to recombinant human GIF, SEQ ID NO. 38, wherein said GIF has the same exact sequence in length and amino acid makeup as the claimed human MIF, SEQ ID NO. 5. The differences between the claimed SEQ ID NO. 5 and the prior art SEQ ID NO. 38 are their functional properties. Whether the prior art SEQ ID NO. 38 has MIF biological activity is irrelevant, it is whether the antibody taught by the prior art, that can specifically bind SEQ ID NO. 38 can also specifically bind SEQ ID No. 5. Since the prior art antibody specifically binds to SEQ ID No. 38, and SEQ ID NO. 5 and SEQ ID NO. 38 are identical in size and amino acid makeup, the prior art antibody would be expected to specifically bind to the instantly claim SEQ ID NO. 5 and therefore an immunoassay for SEQ ID NO. 38 anticipates the claimed invention. Unless applicant can demonstrate that functional differences between MIF and GIF result in the generation of antibodies made against GIF would not specifically bind MIF, they would, because as claimed the antigens the antibodies specifically bind to are structurally identical.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 66-68, 73-75, 81-82, 85, 87-89 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments 11-12-04 have been fully considered but are not found persuasive.

Applicant argues that anti-MIF antibodies are fully disclosed by the instant specification. In addition they argue that since it is well known that GIF and MIF have different post-translational modification patterns which lead to different biological activities, an anti-MIF antibody which specifically binds to MIF will not necessarily bind specifically to GIF. Lastly, Applicant argues the declaration attached by Robert A. Mitchell discloses there is no evidence GIF exists in vivo and as such it is not possible to detect GIF in a naturally derived body sample.

However, antibody specificity is determined by antigen makeup. The recited structure of the claims is a MIF polypeptide that contains SEQ ID NO. 5. The prior art protein is identical in structure. Applicant has provided no evidence demonstrating that an antibody to MIF, SEQ ID NO. 5, will not also specifically bind to GIF, SEQ ID NO. 38. Lastly, there is no requirement by the base claims that the sample is derived from a naturally derived body sample, and even it was the '168 patent clearly teaches in vivo activity of GIF, thereby providing evidence that it is probable GIF exists in vivo.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

February 6, 2005